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BRIAN R. WOODWORTH				
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EXAMINER				
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ART UNIT		PAPER NUMBER		
3746				
NOTIFICATION DATE		DELIVERY MODE		
11/17/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

BRIAN.WOODWORTH@HOSPIRA.COM  
MICHAEL.CRABB@HOSPIRA.COM  
HOSPIRA.DOCKET@CARDINAL-IP.COM

### Office Action Summary

**Application No.**

10/810,123

**Applicant(s)**

GREENE ET AL.

**Examiner**

Philip Stimpert

**Art Unit**

3746

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 October 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,9-12,23-25 and 31-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,9-12,23-25 and 31-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 10/1/10
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 2, 9, 25, 32-34 and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawless et al. (US 5,586,868) in view of Epstein et al. (US 5,464,392) and Likuski et al. (US 4,919,595).
3. Regarding claim 1, Lawless et al. teach a medical pump (10) for use with a pumping chamber (22) comprising a plunger (73) disposed between a passive inlet valve (49a) and a passive outlet valve (49b, see Fig. 8), adapted to intermittently pressurize the pumping chamber (22) during a pumping cycle, the pumping cycle defining an attempted fluid delivery stroke of the pump. Lawless et al. do teach pressure sensors (74, 75), but do not teach a position sensor, processing unit, or memory. Epstein et al. also teach a pressure sensor (308), as well as teaching a position sensor (see col. 19, ln. 40-47, col. 20, ln. 21-31) operatively associated with the pumping element (198, operatively associated through pumping piston 272 (also apparently mislabeled 276 in col. 19, ln. 41)) to detect the position of the pumping element (198), a processing unit (48) in electronic communication with the pressure sensor (40 or 308) and the position sensor, and a memory (404) coupled to the processor unit containing programming code executed by the processing unit to

establish an expected nominal stroke volume associated with the attempted fluid delivery stroke of the pump, set a first frequency based upon a desired dosage rate (col. 6, ln. 67 "minimum infusion rate," frequency is inherent in a dosage rate with this type of pump), process pressure data from the pressure sensor (40 or 308) and position data from the position sensor (col. 28, ln. 44 to col. 29, ln. 3, also equations 1-2 in col. 31) to determine a calculated actual stroke volume of the pump for a pump cycle and, if the calculated actual stroke volume is greater than a given threshold value, to adjust a stroke frequency (col. 27, ln. 25, adjustment is inherent in the determination of the stroke rate, and effectively any value is a threshold value) of the pump from a first frequency to a second, different frequency (as dictated by the equation in col. 27) to compensate for variation between the calculated actual stroke volume and a desired pump flow rate, so as to more closely approach the target rate during subsequent pumping cycles. One of the primary benefits of the pressure sensing apparatus is the ability to precisely and automatically calculate and control the dispensing of medications to a patient (col. 2, ln. 20-32, also col. 23, ln. 4-11). However, Epstein et al. require knowledge of the states of the valves of the pump, thus in order to obtain the benefits of the control system of Epstein et al. in the pump of Lawless et al., a method for detecting valve states must be used in order to perform the necessary calculations for control of the pump. Likuski et al. teach a pumping system in which the states of various passive valves may be determined by analyzing pressure data within the pumping chamber (col. 2, ln. 35-56). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the method of determining the state of a passive valve

as taught by Likuski et al. in the pump control and monitoring system of Epstein et al. in order to obtain precise, automatic control and monitoring in the pump of Lawless et al. Further, it would be obvious to directly connect the pressure sensor of Epstein et al. to the pumping element (73) of Lawless et al. in order to obtain the pressure data required by Likuski et al. since the pressure sensor (36) of Likuski et al. detects the pumping chamber pressure, and the only contact point between the permanent apparatus of Lawless et al. and the disposable cassette thereof is through the plunger. Finally, it would have been obvious to use position sensors to detect the position of the pumping element (30b) of Lawless et al. as taught by Epstein et al.

4. Regarding claim 2, Lawless et al. disclose multiple pressure sensors (74, 75). However, the control system of Epstein et al. requires only a single pressure sensor, thus it would be obvious to use only one sensor, in order to simplify the design and reduce the cost of the parts.

5. Regarding claim 9, Epstein et al. teach that the programming code executed by the processing unit processes pressure data and position data to determine a calculated pressurization volume from a beginning of the compression stroke to the point when the outlet valve opens, and uses the calculated pressurization volume to determine the calculated stroke volume.

6. Regarding claim 25, Lawless et al. teach a medical pump (10) for use with a cassette (10) having a pumping chamber (22) comprising a pumping element, or plunger (73) disposed between a passive inlet valve (49a) and a passive outlet valve (49b, see Fig. 8), adapted to intermittently pressurize the pumping chamber (22) during

a pumping cycle comprising an attempted fluid delivery stroke of the pump. As modified particularly by Epstein et al., Lawless is modified to include a pressure sensor (308) that would be obvious to position directly connected to and in line with the plunger, as well as teaching a position sensor (see col. 19, In. 40-47, col. 20, In. 21-31) operatively associated with the pumping element (198 in Epstein et al., 30b in Lawless et al., operatively associated in Epstein et al. through pumping piston 272 (also apparently mislabeled 276 in col. 19, In. 41)) to detect the position of the pumping element (198) throughout the pumping cycle, a processing unit (48) in electronic communication with the pressure sensor (40 or 308) and the position sensor, and a memory (404) coupled to the processor unit containing programming code executed by the processing unit to establish an expected nominal stroke volume associated with the attempted fluid delivery stroke of the pump, set a first stroke frequency based upon a desired dosage rate and the expected nominal stroke volume (according to the equation in col. 27), then during a pressurization of the pumping chamber for another attempted fluid delivery stroke, to process pressure data from the pressure sensor (40 or 308) and position data from the position sensor (col. 28, In. 44 to col. 29, In. 3, also equations 1-2 in col. 31) to determine a calculated actual stroke volume (also according to the equation in col. 27, along with those of col. 31) of the pump for the pumping cycle and to adjust a stroke frequency (col. 27, In. 25, adjustment is inherent in the determination of the stroke rate, and effectively any value is a threshold value) of the pump from a first frequency to a second, different frequency (as dictated by the equation in col. 27) to compensate for variation between the calculated stroke volume and a desired pump flow rate. As

further taught by Likuski et al., the programming code executed by the processing unit (48) of Epstein et al. processes pressure data from the pressure sensor (40 or 308) in order to identify when the outlet valve (49b) of Lawless et al. has opened.

7. Regarding claims 32 and 38, Lawless et al. teach that the plunger (73) is disposed against the membrane (44) of the pump between the passive valves (49a, 49b) and is adapted to compress/displace the membrane to compress the pumping chamber (Fig. 8).

8. Regarding claims 33 and 39, according to the combination, it is obvious to directly detect the pressure exerted by the plunger, since Likuski et al. teach a pressure sensor directly adjacent to the pumping chamber, and the only element of Lawless which is both non-disposable and adjacent to the pumping chamber is the plunger.

9. Regarding claims 34 and 40, Lawless et al. teach that the plunger (73) is the only plunger used to intermittently pressurize the pumping chamber (22).

10. Claims 10-11, 23, and 24, and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawless et al. in view of Epstein et al. and Likuski et al. as applied to claim 9 above, and further in view of Madsen et al. (US 4,850,805).

11. Regarding claim 10, the previously applied references do not teach the calculation of stroke volume using a ratio of pumping chamber expansion (hereafter, "pumping chamber expansion" will be used interchangeably with "compliance"). The patent to Madsen et al. is directed to a pump control system for a cassette type medical pump. In particular, Madsen et al. address the problem of accurately measuring the

flow volumes of this type of pump, (col. 1, ln. 32-43), especially due to compliance errors. Madsen et al. teach the following method for control of an infusion pump: "The pumping pressure peak during pumping and the pressure minimum during filling are detected to determine the portion of a pumping cycle required to make the transition between these two pressure levels. The difference between the two pressure levels divided by the transition portion of the pumping cycle gives a measure of the compliance of the pump chamber. The ratio of the compliance measure to the total cycle, when multiplied by the nominal chamber volume, gives a measure of unpumped volume, which is subtracted from the nominal volume to give the volume actually pumped during a pump cycle," (abstract, Madsen et al.). Further, Madsen et al. teach that their "control technique gives particularly precise control at low fluid delivery rates where precision is especially important," (Madsen et al., col. 2, ln. 10-12). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the pressure data collected by the pressure sensor of Epstein et al. in the pump of Lawless et al. to calculate the actual volume of fluid pumped, correcting for compliance, in order to more accurately control volumes pumped at low rates. In particular, it would have been obvious to one of ordinary skill in the art to program the processing unit to determine a change in pressurization volume by subtracting the calculated pressurization volume from a nominal pressurization volume, determine a change in stroke volume by multiplying the change in pressurization volume by a ratio of pumping chamber compliance at the end of the compression stroke of the pump to the

compliance at the start of the compression stroke, and determine the calculated stroke volume based on the change in stroke volume.

12. Regarding claim 11, Lawless et al. teach a cassette (10) for defining the pumping chamber (22).

13. Regarding claim 23, Lawless et al. teach a medical pump (10) for use with a cassette (10) having a pumping chamber (22) comprising a pumping element, or plunger (30b), adapted to intermittently pressurize the pumping chamber (22) during a pumping cycle comprising an attempted fluid delivery stroke of the pump, and a passive outlet valve (49b). As modified particularly by Epstein et al., Lawless is modified to include a pressure sensor (308), as well as teaching a position sensor (see col. 19, ln. 40-47, col. 20, ln. 21-31) operatively associated with the pumping element (198 in Epstein et al., 30b in Lawless et al., operatively associated in Epstein et al. through pumping piston 272 (also apparently mislabeled 276 in col. 19, ln. 41)) to detect the position of the pumping element (198) throughout the pumping cycle, a processing unit (48) in electronic communication with the pressure sensor (40 or 308) and the position sensor, and a memory (404) coupled to the processor unit containing programming code executed by the processing unit to establish an expected nominal stroke volume associated with the attempted fluid delivery stroke of the pump, set a first stroke frequency based upon a desired dosage rate and the expected nominal stroke volume (according to the equation in col. 27), then during a pressurization of the pumping chamber for another attempted fluid delivery stroke, to process pressure data from the pressure sensor (40 or 308) and position data from the position sensor (col. 28, ln. 44 to

col. 29, ln. 3, also equations 1-2 in col. 31) to set a stroke frequency (col. 27, ln. 25) for a desired dosage rate based on a nominal stroke volume ( $A \cdot 100$  or  $A \cdot 88$ , col. 31, ln. 12-18), determine a calculated pressurization volume from a beginning of a compression stroke of the pumping cycle to the point when the outlet valve opens (col. 31, relation 1,  $A \cdot N2$ ), and determine a change in pressurization volume by subtracting the calculated pressurization volume from a nominal pressurization volume (col. 31, relation 1). As further taught by Likuski et al., the programming code is executed to identify by a slope change in pressure data (paragraph 124) when an outlet valve (49b) of the pumping chamber of Lawless et al. has opened. As further taught by Madsen et al., the programming code is executed to determine a change in stroke volume by multiplying the change in pressurization volume by a ratio of pumping chamber compliance at the end of the compression stroke of the pumping cycle to the pumping chamber compliance at the start of the compression stroke of the pumping cycle, determine a calculated stroke volume based on the change in stroke volume, and adjust the stroke frequency to compensate for variation between the calculated stroke volume and the nominal stroke volume.

14. Regarding claim 24, Lawless et al. teach a cassette (10) for defining the pumping chamber.

15. Regarding claim 35, Lawless et al. teach that the plunger (73) is disposed against the membrane (44) of the pump between the passive valves (49a, 49b) and is adapted to compress displace the membrane to compress the pumping chamber (Fig. 8).

16. Regarding claim 36, according to the combination, it is obvious to directly detect the pressure exerted by the plunger, since Likuski et al. teach a pressure sensor directly adjacent to the pumping chamber, and the only element of Lawless which is both non-disposable and adjacent to the pumping chamber is the plunger.

17. Regarding claim 37, Lawless et al. teach that the plunger (73) is the only plunger used to intermittently pressurize the pumping chamber (22).

18. Claims 12 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawless et al. in view of Epstein et al., Likuski et al., and Madsen et al. as applied to claim 10 above, and further in view of Holst et al. (US 2003/0055375).

19. Regarding claim 12, the previously combined references do not teach the practice of averaging multiple calculated stroke volumes to produce a single calculated stroke volume. The patent to Holst et al. is directed to a pumping control method for a cassette pump. In particular, Holst et al. teach the acquisition of pressure samples, and that "the plurality of samples are averaged to minimize any pressure sensing variations," (paragraph 35). As discussed above, the calculated stroke volume is in part dependent upon the pressure data. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a calculated stroke volume comprising multiple calculated stroke volumes averaged together, in order to minimize the effects of pressure sensing variations in the calculations.

20. Regarding claim 31, Madsen et al. teach that the cassette volume (nominal cassette volume) may be empirically determined (col. 8, ln. 24-27). As such, one of

ordinary skill would expect measuring error to take place, thus engendering the use of averages (taught above with respect to pressure, but certainly of broader applicability) to minimize the effects of those errors. Therefore it would have been obvious to use an average of multiple nominal pressurization volumes.

### ***Response to Arguments***

21. Applicant's arguments, see page 8, filed 1 October 2010, with respect to the rejection(s) of claim(s) 1, 2, 9-12, 23-25, and 31 under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

However, upon further consideration, a new ground(s) of rejection is made in view of Likuski et al.

22. The patent to Likuski et al. more clearly teaches the use of pressure data in the analysis of valve states.

23. Regarding the plunger limitations, the previous position taken by the examiner that element (30b) represented the plunger of Lawless, was a mischaracterization of that reference. The plunger (73) currently cited satisfies the limitations of the claims.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Philip Stimpert whose telephone number is (571)270-1890. The examiner can normally be reached on Mon-Fri 7:30AM-4:00PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Devon Kramer can be reached on (571) 272-7118. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Devon C Kramer/  
Supervisory Patent Examiner, Art  
Unit 3746

/P. S./  
Examiner, Art Unit 3746  
5 November 2010